PCRM PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE
5100 WISCONSIN AVENUE, N.W. • SUITE 404
WASHINGTON, DC 20016
T: (202) 686-2210 • F: (202) 686-2216
PCRM@PCRM.ORG • WWW.PCRM.ORG

November 17, 2000

The Honorable Carol Browner
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on Test Plan for Irgafos 168 (tris(2,4-di-(tert)-butylphenyl)phosphite)

Dear Administrator Browner:

The following comments on the test plan for Irgafos 168 (tris(2,4-di-(tert)-butylphenyl)phosphite) are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These animal protection and environmental organizations have a combined membership of more than nine million Americans.

The summary submitted by Ciba Specialty Chemicals Corporation appropriately does not call for any additional testing on this well-characterized chemical. The available data are more than adequate under High Production Volume (HPV) Program guidelines. However, the presentation of the test plan raises some questions regarding compliance with the original HPV framework agreement in which sponsors committed to performing a thorough review of existing data. These concerns include:

- The summary presents minimal data and little discussion of its ability to meet the HPV standards and obviate the need for more tests. No qualitative information on the compound's application and behavior is provided.
- Ciba failed to identify the existing information on Irgafos 168, as studies in the scientific literature and government databases describe the environmental fate and transport of this chemical.
- This compound is already registered as an FDA food contact substance and more toxicological information may be available. Accordingly, we have submitted a Freedom of Information Act (FOIA) request for this information.
- Ciba failed to compare Irgafos 168 with other similar chemicals to form a group of phenol compounds. Irgafos 168 is one of many phenyl-phosphorus antioxidant stabilizers that are included in the HPV Program, and would logically fall into the same group in the development of a test plan.

The EPA needs to play a strong role in requiring that companies perform a thorough review of the literature and present all available information on the proposed chemicals. The EPA also needs to assume a stronger role in promoting cooperation among participants with respect to chemical category formation. We ask the

EPA to inform us how it intends to foster this cooperation in the development of chemical categories so that unnecessary, expensive, and poorly conceived testing is avoided. While Ciba does not call for additional testing, we are concerned that a regulatory review may disagree with Ciba's claim that no additional tests are necessary. We believe that additional testing of this well-understood compound would be redundant and would not contribute to a greater understanding of the public health impact of Irgafos 168. It should be noted that in the event additional testing is called for, the testing must be deferred until November 2001 or later, as Irgafos 168 is an individual chemical.

I can be reached via telephone at 202-686-2210, ext. 302, or via e-mail at <ncardello@pcrm.org>. Correspondence should be sent to my attention at the following address: PCRM, 5100 Wisconsin Ave., Suite 404, Washington, DC 20016. I look forward to your response.

Sincerely,

Nicole Cardello, MHS
Research Coordinator

cc: The Honorable Robert C. Smith
The Honorable F. James Sensenbrenner, Jr.
The Honorable Ken Calvert
The Honorable Jerry Costello
Council on Environmental Quality

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General Comments on the Test Plan for Irgafos 168

The Ciba Specialty Chemicals Corporation has provided available in-house study results on Irgafos 168 that addresses each health endpoint of the SIDS battery and therefore appropriately has not called for more tests. However, the summary does raise some concern regarding the original HPV framework agreement in which sponsors committed to conducting a comprehensive review of existing data. We are providing further justification for Ciba's contention that no additional tests are needed under HPV guidelines.

Irgafos 168 is a hydrolytically stable phosphite processing stabilizer. It is a hydrophobic, high molecular weight (MW= 646.9) organophosphite of low volatility and is particularly resistant to hydrolysis. These physico-chemical properties most likely explain the relatively low toxicity to animals dosed with this substance. For example, the oral LD-50 was found to be greater than 6000 mg/kg bodyweight, the dermal LD-50 was found to be greater than 2000 mg/kg bodyweight, and no evidence of mutagenicity was seen.

Other Existing Environmental Fate and Transport Studies

Several studies in the scientific literature provide additional information on the environmental fate and transport of Irgafos 168, as presented in Table 1. Additional detail on the transport and behavior in soil is provided by a study by Fischer *et al*.[1] Incorporation of results from this study may enhance the theoretical fugacity calculation that Ciba provided in its summary.

The migration of antioxidant additives from food-packaging material has recently become a subject of interest. Studies by Garde *et al.* and Bourges *et al*. examine the fate and transport of Irgafos 168 from food-packaging substances. Inclusion of these study results would provide additional information on factors influencing environmental fate and transport of these chemicals and potential exposure scenarios.[2,3]

Chemical Categories

Ciba failed to compare Irgafos 168 with other similar chemicals to form a chemical category. Irgafos 168 is one of many phenyl-phosphorus antioxidant stabilizers that are included in the HPV Program and would logically fall into the same group in the development of a test plan. A brief list of potential compounds for this group (along with their sponsors) is presented in Table 2.[4] We have already submitted suggestions for forming this chemical category and are concerned that companies are not cooperating in the development of chemical groups.[5,6,7] We are asking the EPA to inform us how it intends to foster cooperation in category formation so that unnecessary, expensive, and poorly conceived testing is avoided.

Conclusion

Although Ciba Specialty Chemicals Corporation has presented its in-house data and appropriately has not called for any testing, interpretation of study results and a comprehensive review of existing data were needed

to provide a complete summary of the chemical's properties, behavior, and toxicity. Additionally, the inclusion of Irgafos 168 into a chemical category should be considered.

References

1. Fischer K., Norman S, Freitag D. Studies of the behaviour and fate of the polymer-additives octadecyl-3-(3,5-di-t-butyl-4-hydroxyphenyl)proprionate and tri-(2,4-di-t-butylphenyl)phosphite in the environment. Chemosphere 1999;39(4):611-25.
2. Garde JA, Catala R, Gavara R. Analysis of antioxidants extracted from polypropylene by superficial fluid extraction. Food Addit Contam 1998;15(6):701-8.
3. Bourges F, Bureau G, Pascat B. Effects of electron beam irradiation on the migration of antioxidants and their degradation from commercial polyproylene into food simulating liquids. Food Addit Contam 1993;10(4):443-52.
4. Note: This table is not a comprehensive list of compounds that could be included in a group, but rather an example to provide a starting point for discussions. Some compounds are listed multiple times due to multiple sponsors.
5. Letter to Carol Browner from People for the Ethical Treatment of Animals dated August 21, 2000.
6. Letter to Carol Browner from People for the Ethical Treatment of Animals dated October 11, 2000. Comments on "Robust Summary on Phosphorus Acid, Cyclic Neopentanetetrayl Diphenyl Ester."
7. Letter to Carol Browner from Physicians Committee for Responsible Medicine dated October 11, 2000. Comments on "Robust Summary on Tris (Nonylphenyl) Phosphite."

Table 1. Literature Review of Irgafos 168

Author	Title	Source	Subject
Fisher *et al.*, 1999	Studies of the behaviour and fate of the polymer-additives octadecyl-3-(3,5-di-t-butyl-4-hydroxyphenyl)proprionate and tri-(2,4-di-t-butylphenyl)phosphite in the environment.	Chemosphere	environmental fate and transport
Garde *et al.*, 1998	Analysis of antioxidants extracted from polypropylene by superficial fluid extraction.	Food Addit Contam	fate/transport; migration to food substances
Bourges *et al*., 1993	Effects of electron beam irradiation on the migration of antioxidants and their degradation from commercial polyproylene into food simulating liquids.	Food Addit Contam	fate/transport; migration to food substances

Table 1. Literature Review of Irgafos 168

CAS Number	Compound	Sponsor
101020	Phosphorous acid, triphenyl ester	Chemical Manufacturers Association (CMA) Health, Environmental, and Research Task Group (HERTG) [F] 2001
101020	Phosphorous acid, triphenyl ester	Phosphite Producers HPV Consortium [F] 2003
101020	Phosphorous acid, triphenyl ester	Dover Chemical Corporation [F] 2003
115866	Phosphoric acid, triphenyl ester	Chemical Manufacturers Association (CMA) Aryl Phosphates Panel [P]
115866	Phosphoric acid, triphenyl ester	Akzo Nobel Functional Chemicals LLC — Phosphorus Chemicals [F] 2003
115866	Phosphoric acid, triphenyl ester	Bayer AG Corporation [I]
144354	Phosphorous acid, cyclic neopentanetetrayl diphenyl ester	General Electric (GE) [F] 2000
20227536	Phosphorous acid, 2-tert-butyl-.alpha.-(3-tert-butyl-4-hydroxyphenyl)-p-cumenyl bis(p-nonylphenyl) ester	Chemical Manufacturers Association (CMA) Rubber and Plastics (RAPA) Panel [F] 2003
25550985	Phosphorous acid, diisodecyl phenyl ester	Phosphite Producers HPV Consortium [F] 2001
25550985	Phosphorous acid, diisodecyl phenyl ester	Dover Chemical Corporation [F] 2001
26523784	Phenol, nonyl-, phosphite (3:1)	Phosphite Producers HPV Consortium [F] 2000
26523784	Phenol, nonyl-, phosphite (3:1)	CK Witco Corp [F] 2003
26523784	Phenol, nonyl-, phosphite (3:1)	Dover Chemical Corporation [F] 2000
26544230	Phosphorous acid, isodecyl diphenyl ester	Phosphite Producers HPV Consortium [F] 2001
26544230	Phosphorous acid, isodecyl diphenyl ester	Dover Chemical Corporation [F] 2001
26741537	Phosphorous acid, cyclic neopentanetetrayl bis(2,4-di-tert-butylphenyl) ester	General Electric (GE) [F] 2002
31570044	Phenol, 2,4-di-tert-butyl-, phosphite (3:1)	Ciba Specialty Chemicals Corporation - Additives [F] 2000
31570044	Phenol, 2,4-di-tert-butyl-, phosphite (3:1)	Ciba Specialty Chemicals Corporation - Additives [F] 2000